PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q76105
Hirohiko TSUZUKI, et al.	
Application No.: 10/612,955	Group Art Unit: 1651
Confirmation No.: 4760	Examiner: Satyendra K. Singh
Filed: July 7, 2003	

For: CARRIER FOR CELL CULTURE

DECLARATION UNDER 37 C.F.R. § 1.132 of HIROHIKO TSUZUKI

Mail Stop Amendment
Commissioner for Patents
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Sir:

I, Hirohiko Tsuzuki, hereby declare and state:

I am a citizen of Japan and the first-named inventor of the present application.

I received a master's degree of technologies from the University of Tokyo in March 1988.

In April 1998, I accepted employment with Fuji Photo Film Co., Ltd. (now FUJIFILM Corp.), and since that time I have been employed as a research chemist with Fuji. I have been engaged particularly on research relating to tissue cultures, at Fuji's Ashigara Research Laboratory.

I have reviewed the Office Action dated September 13, 2006. I am aware that claims 12-15 and 17-19 are rejected under 35 U.S.C. 103(a) over Hara et al. (U.S. Patent No. 6,821,107) in view of Huguet & Dellacherie and Clapper et al. (U.S. Patent No. 5,512,474).

In support of the patentability of our invention, I conducted the following experiments:

Experimentation

Using the alginic acid gel membrane obtained by the method of Example 6 of the present specification, test carrier samples were prepared by applying chitosan and alternatively other materials (i.e., polyacrylaraide, polymethylmethacrylate, and polystyrene) followed by coating with collagen.

Sample No. 502 was prepared in the same manner as Example 6, except that alginic acid gel was immersed in an aqueous solution of polyacrylamide (1% by weight) for 1 hour. For Samples Nos. 503 and 504, the alginic acid gel obtained was dried and then immersed in a solution of tetrahydrofuran/water (95/5 % by volume) containing 1% by weight of polymethylmethacrylate or polystyrene for 1 hour, and the resulting membrane was dried and further washed with water for over 1 hour, and used for preparation of the samples.

The samples were evaluated as follows:

(1) Strength

Each sample was cut down to 3 x 3 cm and immersed in culture medium for three days. The sample was handled by a pincette and the condition of the sample was evaluated on the basis of the following criteria;

o: the sample can be picked up and not fragmented or broken;

Δ: the sample is sometimes torn after being picked up;

x: the sample is weak and easily broken, and cannot be picked up.

(2) Transparency

Each sample was cultured in the same manner as Example 5, and the cell culture was observed to evaluate visibility on the basis of the following criteria:

⊡: the sample is transparent and the cells can be satisfactorily observed without any problem;

o: the sample has a slight turbidity, but the cells can be observed without any practical problem;

Δ: the sample has turbidity, and some parts of the cells are not observable;

x : the sample is entirely turbid or partly turbid, and the cells are not observable.

Experimental Results

Sample	Material		Strength	Transparency
203	chitosan	Invention	O	□
502	polyacrylamide	Comparative	X	o
503	polymethylmetbacrylate	Comparative	o	Δ
504	polystyrene	Comparative	o	X

As seen in the above table of Experimental Results, sample 203 embodying the present invention provided superior results in terms of strength and transparency relative to samples 502-504. For example, sample 203, applied with chitosan, could be picked up without fragmentation or breakage and was transparent, with cells clearly visible. Sample 502, applied with polyacrylamide, could not be handled but retained cellular visibility. Sample 503, applied with polymethylmetbacrylate, could be handled without fragmenting or breaking, but visibility was reduced. Sample 504, applied with polystyrene, was strong but the sample was turbid, and the cells were not observable.

In my opinion, the combination of superior properties obtained with chitosan in the present invention, namely the combination of strength and transparency, would have been unexpected in view of the prior art.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: Jan 16, 2007

Hirohiko Tsuzuki
Dr. Hirohiko Tsuzuki